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First Circuit Holds that Scienter Requires Knowledge That Non-Disclosure Risked Misleading Investors, Not Just Knowledge of Omitted Facts, in Brennan v. Zafgen, Inc. (April 7, 2017)

Securities Litigation Legal Update

In *Brennan v. Zafgen, Inc.,* -- F.3d --, 2017 WL 1291194 (1st Cir., April 7, 2017), the First Circuit affirmed a District of Massachusetts decision dismissing claims against Zafgen, Inc., a biopharmaceutical developer, and its CEO, Dr. Thomas Hughes. Judge Stahl, writing for a panel that included retired Supreme Court Justice Souter (sitting by designation), concluded that plaintiffs' complaint did not allege facts giving rise to the "cogent and compelling" inference of scienter required by the Reform Act. *Id.* at *1 (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007)).

Between August 2012 and May 2013, before Zafgen went public, the company conducted a Phase II trial of an anti-obesity drug called Beloranib. As the trial progressed, four patients in the trial who were receiving the drug suffered adverse "thrombotic"—i.e., blood-clotting—events of varying severity. Third-party clinical investigators classified two of these adverse thrombotic events as "superficial," and the other two events as "serious." In April 2014, as Zafgen was preparing for a June 2014 IPO, it disclosed the two serious events, but not the two superficial events, in its Form S-1 Registration Statement. *Id.* at *1-2.

In mid-October 2015, Zafgen's share price began to decline, falling from $34.76 on October 12 to $15.75 at close of trading the next day. On October 15, Zafgen disclosed that a patient in its ongoing Phase III trial of Beloranib had died; and on October 16, the company confirmed that this patient had been treated with the drug (rather than a placebo), and that the FDA had placed Beloranib on a partial clinical hold. Also on October 16, 2015, Zafgen's chief medical officer, Dr. Dennis Kim, disclosed for the first time the two superficial adverse events from the Phase II trial that was

conducted in 2012-2013. By the end of trading on October 16, the price of Zafgen stock had dropped to $10.36. *Id.* at *2.

The plaintiffs in *Brennan* sued Zafgen and Dr. Hughes on behalf of a putative class consisting of all persons and entities who bought Zafgen stock between its IPO on June 19, 2014 and October 16, 2015, when the company announced the FDA's partial clinical hold. *Id.* at *3. They argued that the company had made misleading statements about its Beloranib trial in ten different documents that were signed by Dr. Hughes, and they asserted claims under Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5. Specifically, the plaintiffs claimed that the challenged statements were misleading because they failed to mention the two superficial adverse events from the Phase II trial, which were disclosed for the first time by Dr. Kim on October 16, 2015. *Id.* at *1-3. (Despite alleging material omissions in Zafgen's Registration Statement, plaintiffs did not assert Securities Act claims.)

The district court dismissed plaintiffs' complaint on the ground that it failed to adequately plead a "strong inference" of scienter, as is required by the Reform Act. In doing so, the district court placed particular emphasis on the materiality of the two superficial adverse events, which it described as "marginal," thereby weakening any inference of scienter. *Id.* at *4.

On appeal, the plaintiffs argued that they had, in fact, satisfied the Reform Act's scienter requirement, because they had pled that defendants (1) knew, or were reckless in not knowing, about news and scientific articles purportedly showing a link between Beloranib and adverse thrombotic events; and (2) had a motive to commit securities fraud, as shown by Zafgen's compensation structure, and by "heavy" insider sales before the patient death was announced. *Id.* at *5.

Regarding the news and scientific articles cited by plaintiffs, the First Circuit noted that "'[t]he key question … is not whether defendants had knowledge of certain undisclosed facts, but rather whether [they] knew or should have known that their failure to disclose those facts' risked misleading investors." *Id.* (quoting *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Waters Corp.*, 632 F.3d 751, 758 (1st Cir. 2012)). In this case, the cited articles "may [have] suggest[ed]" that the defendants were aware of a link between Beloranib and thrombotic events. But the articles did not demonstrate that the defendants "deliberately or recklessly risked misleading investors" by not disclosing the two superficial events from the Phase II trial until October 16, 2015. *Id.*

Turning to plaintiffs' motive allegations relating to insider trading and Zafgen's compensation structure, the First Circuit agreed with the district

court that "the strength of the insider trading allegations drifts towards the marginal end of that spectrum because [CEO] Hughes and all other Zafgen insiders kept the vast majority of their Zafgen holdings." *Id.* at *6 (observing that after accounting for vested options, Dr. Hughes retained at least 93 percent of his Zafgen stock, and every other insider identified in the complaint retained at least 85 percent). In light of this fact, the district court was correct in determining that the plaintiffs' insider trading allegations "d[id] not alter the conclusion that the complaint as a whole fails to raise a strong inference of scienter." *Id.*

As for the plaintiffs' arguments regarding Zafgen's compensation structure, the First Circuit found that the complaint's allegations offered no basis for inferring fraudulent intent, but showed only "the usual concern by executives to improve financial results." *Id.* (quoting *In re Cabletron Sys., Inc.,* 311 F.3d 11, 39 (1st Cir. 2002)). An allegation that a defendant had motive and opportunity to commit fraud, or that a corporation "rewards [its executives for] the achievement of corporate goals," does not satisfy the Reform Act "without something more." *Id.*

The First Circuit also discussed several other considerations that "bolster[ed]" its conclusion that the complaint's allegations did not give rise to a sufficiently strong inference of scienter. These included the fact that (1) the materiality of the two undisclosed superficial adverse events was "marginal," which "tends to undercut the argument that the defendants acted with the requisite intent … in not disclosing [them]," *id.* at *7 (quoting *In re Ariad Pharm. Sec. Litig.,* 842 F.3d 744, 751 (1st Cir. 2016)); and (2) Zafgen's disclosures before and during the class period mentioned the two serious thrombotic events from the Phase II study, and also stated that the company would not disclose all adverse events as they occurred, which "weaken[ed] the complaint's scienter showing," *id.* at *8.

Having thus concluded that the plaintiffs' allegations, considered as a whole, did not give rise to a "cogent and compelling" inference of scienter, the First Circuit affirmed the dismissal of plaintiffs' Section 10(b) claim as well as their Section 20(a) claim against Dr. Hughes, which was derivative of the former. *Id.*